

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PUREWICK CORPORATION,

Plaintiff/Counterclaim Defendant,

v.

SAGE PRODUCTS, LLC,

Defendant/Counterclaim Plaintiff.

C.A. No. 19-1508-MN

REDACTED - PUBLIC VERSION
(Filed May 26, 2022)

**SAGE'S ANSWERING BRIEF IN OPPOSITION TO
PUREWICK'S POST-TRIAL MOTIONS**

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Reference	Description
Br.	PureWick’s Opening Brief in Support of Its Post-Trial Motions
Ex.	Exhibits 1-32 filed concurrently herewith. In some cases, exhibits from summary judgment are referenced to avoid a voluminous submission. Trial exhibits shall be provided separately to the Court in accordance with the Court’s Preferences & Procedures for Civil Cases.
Tr.	Final Trial transcripts docketed at D.I. 326 to 330. Sage notes that its post-trial motions and briefing (D.I. 332) filed on May 5, 2022 cite “Tr.”, which refer to an earlier version of the Court’s transcripts that are off from the final trial transcripts by one line in some places.
Alexander, ¶	Declaration of Nicholas Alexander, Division Counsel of Sage business unit, filed concurrently herewith.
Farrell, ¶	Declaration of Eric Farrell, Senior Director of Marketing at Sage, filed concurrently herewith.
Newman, ¶	Declaration of Dr. Diane Newman, Sage’s technical expert, filed concurrently herewith.
Thomas, ¶	Declaration of Vincent Thomas, Sage’s damages expert, filed concurrently herewith.
PrimaFit	Sage’s PrimaFit product at issue at trial, accused of infringing the 376, and 989 Patents (JTX14, JTX14E)
PrimoFit	Sage’s PrimoFit product at issue at trial, accused of infringing the 407 Patent (JTX15)

* Unless otherwise noted, all emphases herein have been added. Citations and quotations in case citations have generally been omitted.

NATURE AND STAGE OF PROCEEDINGS

PureWick alleged that the PrimaFit product (JTX14, 14E), which launched in late 2017, infringed the 508, 376, and 989 patents, and PrimoFit (JTX15) infringed the 407 patent. Despite having a 2012 patent, PureWick deliberately waited years to file suit. (Ex. 1.) When it finally sued in 2019, rather than seek an injunction, PureWick again waited years, allowing Sage to build the market and invest in research and development for its PrimaFit product to Sage's prejudice.

In early 2020, shortly after the lawsuit was filed, Sage contacted PureWick to advise that it had strong defenses including more than a good faith basis of noninfringement and invalidity. (Ex. 2.) Sage explained that the 508 patent was not infringed and invalid in view of Mahnensmith and that the 376, 989, and 407 patents were not infringed and invalid in view of Van Den Heuvel and Suzuki. (*Id.*) Sage asked PureWick to withdraw its case. (*Id.*) Sage presented its good faith defenses throughout the case and even prevailed on theories at the Patent Office. Indeed, the PTAB issued a final written decision finding the 508 patent invalid based on the very reference identified in Sage's 2020 letter to PureWick (Mahnensmith) and other art. (Exs 2-5.) The PTAB agreed with Sage's understanding of the prior art and repeatedly credited the testimony of Sage's expert, Dr. Diane Newman, finding her testimony "credible, well reasoned and entitled to significant weight." (Ex. 4 at 36, 41, 43, 44, 51, 55, 56.) In contrast, the PTAB rejected the testimony of PureWick's expert (Jezzi) concluding his theories were "based entirely on speculation, inconsistent with how a [POSA] would have understood [the art], and thus is not credible." (*Id.* at 35, 38.)

In the meantime, in 2019, Sage developed and launched a non-infringing alternative ("NIA") (PrimaFit 2.0). (Ex. 10, 272-275.) Sage identified 2.0 as an NIA early in discovery and produced numerous 2.0 documents, and PureWick deposed many witnesses about it including about its 2019 launch. But PureWick never tried to add 2.0 into the case as an infringing product. Sage proceeded to full launch and discontinued manufacture of the accused PrimaFit product in

2021. And, contrary to PureWick’s false statements, Sage repeatedly told PureWick before trial that the accused PrimaFit was no longer manufactured. (Ex. 11, ¶7; D.I. 277, Br. 10; Sect. I.E.)

After the Court found fact issues for the jury on the issues of infringement and invalidity (D.I. 287), trial occurred from March 28 to April 1, 2022. PureWick presented no evidence that Sage acted improperly after the 376 and 989 patents issued in 2019. PureWick’s only evidence focused on acts that occurred in 2016—years before any patents issued. PureWick claimed “copying” but there was no evidence about what PureWick products were “copied,” much less that anyone had access to any patented PureWick products. At trial, PureWick never rebutted Sage’s evidence of invalidity in view of Van Den Heuvel and presented a theory on Suzuki that was inconsistent with the PTAB’s IPR ruling. (Tr. 942-944; Ex. 4 at 52-55.) Moreover, though Sage had long contended that PureWick’s disclosure of its products in 2015 was invalidating (and deposition testimony confirmed those facts (D.I. 204 at 14-17)), at trial, the Newtons changed their deposition testimony, surprisingly claiming their products were failures that had never been sold in 2015 (despite winning “2015 New Product of the Year”). (D.I. 312; DTX519.) After trial, Sage renewed its JMOL and moved for a new trial (D.I. 332); PureWick filed the present motions.

SUMMARY OF THE ARGUMENT AND ARGUMENT

PureWick’s post-trial motions should be denied. PureWick is not entitled to an injunction. The public and Sage will be harmed if any PrimaFit products are barred from the market. PureWick cannot claim irreparable harm due to its decision to wait years to sue, and monetary damages compensated it. PureWick’s motion for enhanced damages, a rare remedy in this District, should be denied as there is no egregious conduct by Sage. PureWick’s allegations of years-old, pre-issuance “copying” are legally irrelevant and its “misconduct” theories are baseless. Sage acted in good faith with noninfringement and invalidity defenses and discontinued the PrimaFit product found to infringe. PureWick’s motions for prejudgment interest and an ongoing PrimoFit royalty

overreach, and its motion for supplemental PrimaFit damages is unwarranted because the verdict encompassed all damages. PureWick's motion to amend the judgment is contrary to the law.

I. A PERMANENT INJUNCTION ON PRIMAFIT SHOULD BE DENIED

The Supreme Court rejected PureWick's argument that a prevailing party "may normally expect to" secure an injunction. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 394 (2006). Rather, "[e]very injunctive case must be considered according to its unique facts." *ActiveVideo Netwks v. Verizon Commc'ns*, 694 F.3d 1312, 1338 n.6 (Fed. Cir. 2012). PureWick failed to prove that the four *eBay* factors are satisfied. *Nichia v. Everlight*, 855 F.3d 1328, 1341 (Fed. Cir. 2017).

A. PureWick Waited Years To Sue And Cannot Establish Irreparable Harm

"[D]elay in bringing an infringement action and seeking a preliminary injunction ...suggest[s] that the patentee is not irreparably harmed...." *Apple v. Samsung*, 678 F.3d 1314, 1325 (Fed. Cir. 2012). "Injunctive relief has been found to be inappropriate where a Plaintiff has had no apparent urgency in requesting it." *Waters Corp. v. Agilent Techs. Inc.*, 410 F. Supp. 3d 702, 714 (D. Del. 2019). Sage launched PrimaFit in 2017. (Tr. 605.) Despite having a patent issued in 2012 (JTX1) and knowing about PrimaFit before it launched (DTX140; Ex. 6; Ex. 8), PureWick delayed for years in filing suit and let PrimaFit stay on the market for five years before seeking an injunction. Indeed, in 2017, PureWick contacted Sage about PrimaFit yet never made any allegations about patent infringement, relevant patent applications, or irreparable harm. (Ex. 8.) Instead, PureWick sat by for five years and watched Sage invest time, money, and resources into PrimaFit, including investing millions in manufacturing improvements (Ex. 12 at 43-45; Farrell, ¶4). This was no accident, but a calculated decision by PureWick. As late as 2019, PureWick assessed the "financial benefit of going after Sage," concluding that it was "not sure it is [worth it] right now". (Ex. 1.) Sage asked about the delay but PureWick offered no explanation. (Ex. 7 at 28-29.) "Absent a good explanation...17 months is a substantial period of delay," which "undercuts

[the] claim of irreparable harm.” *High Tech Med. Instr. v. New Image Indus.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995). PureWick’s wait-and-see strategy, coupled with its five-year failure to seek an injunction, “cuts against a notion” that it suffers irreparable harm. *Waters*, 410 F. Supp. 3d at 715.

PureWick argues that the status of the parties as “competitors” is sufficient (Br. 17), but “equitable principles do not permit such broad classifications” and irreparable harm must be proven. *eBay*, 547 U.S. at 393. PureWick also claims that the willfulness verdict shows irreparable harm (Br. 18), but “willful[ness] is not relevant to the question of irreparable harm.” *Cordis v. Adv. Cardio. Sys.*, No. 97–635–SLR, 1999 WL 805283, *8 n.4 (D. Del. Sept. 10, 1999).

The fact is PureWick cannot be irreparably harmed because the adjudicated PrimaFit is no longer manufactured for sale (Farrell, ¶10)—a fact that PureWick knew before trial (see §I.E.). *XpertUniverse v. Cisco Sys.*, No. 09-157-RGA, 2013 WL 6118447, at *12 (D. Del. Nov. 20, 2013). Moreover, PureWick’s assertion of harm fails because, “to prove irreparable injury, a patentee must show...a sufficiently strong causal nexus relates the alleged harm to the alleged infringement,” namely that “the infringing feature drives consumer demand for the accused product.” *Bio-Rad Labs., Inc. v. 10X Genomics*, 967 F.3d 1353, 1377-78 (Fed. Cir. 2020); *TEK Glob., S.R.L. v. Sealant Sys.*, 920 F.3d 777, 792 (Fed. Cir. 2019). Here, PureWick identifies no nexus between any harm and the 376/989 patents. PureWick’s witness (Gohde) admitted that he did not know “whether or not the reason why hospitals buy the PureWick has anything to do with the patents in this lawsuit” and testified that “a variety of factors” drive sales. (Tr. 370-75, 576-77, 896-899, 364-365.) What drove demand for PrimaFit is non-patented features that made PrimaFit superior in fit, securement, and performance. (Newman, ¶¶20-31; Farrell, ¶¶6-8; DTX142; Tr. 599-601, 669-683, 730-732, 895-901; DTX165, DTX193, PTX42, PTX486.)

B. Monetary Damages Are Adequate To Compensate PureWick

A patentee “ha[s] a burden to iterate specific reasons why [the defendant]’s infringement

cannot be compensated for with a money award.” *Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440, 444 (D. Del. 2007). PureWick provided none, and its expert testified that money damages were adequate. Tr. 544. PureWick also failed to explain how the jury’s damages award, which covers the full period of alleged infringement through November 2021 (when Sage stopped manufacturing, Farrell, ¶3), does not adequately compensate it. The adequacy of monetary damages is further demonstrated by PureWick’s calculated delay in filing suit. Ex. 1; *Chestnut Hill Sound v. Apple*, No. 15-261-RGA, 2015 WL 6870037, at *5 (D. Del. Nov. 6, 2015).

C. The Public Interest Will Be Harmed By An Injunction

PureWick cannot prove that “the public interest would not be disserved by a permanent injunction.” *eBay*, 547 U.S. at 391. “[F]or good reason, courts have refused to permanently enjoin activities that would injure the public health,” and the public interest factor is often dispositive in denying an injunction for medical devices. *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App’x. 928, 935 (Fed. Cir. 2004). That is because there is an “obvious concern of depriving the public of the best and safest medical devices by limiting competition.” *Cordis Corp. v. Bos. Sci. Corp.*, No. 03-027-283-SLR, 2003 WL 22843072, at *2 (D. Del. Nov. 21, 2003) (denying injunction). In *Advanced Cardiovascular Sys., Inc. (“ACS”) v. Medtronic Vascular*, 579 F. Supp. 2d 554, 561 (D. Del. 2008), the court denied an injunction because, though the parties were direct competitors, evidence showed that defendant’s products included preferred features. *See also Cordis*, 99 F. App’x. at 935-36 (“the record contain[ed] evidence that some doctors preferred” defendant’s product); *Am. Cyanamid Co. v. U.S. Surg. Corp.*, 833 F. Supp. 92, 134 (D. Conn. 1992) (“the public will be harmed by an injunction [if] some physicians prefer’ the accused medical...product.”); *Datascope v. Kontron*, 611 F. Supp. 889, 895 (D. Mass. 1985), *aff’d*, 786 F.2d 398 (Fed. Cir. 1986).

Here, the evidence is overwhelming that the public would be harmed by an injunction against PrimaFit given that PrimaFit includes many features preferred by clinicians that are not

available in other market products. (Newman, ¶¶20-31.) It is in the best interests of patients and caregivers to have multiple options because “[p]atients have different anatomies...and different incontinence challenges and benefit from a choice of options in urinary incontinence products.” (*Id.*, ¶¶1, 17-19, 48; Tr. 727-728.) An injunction would mean that clinicians would lose the potential option of a robust, fully-featured product.¹ Dr. Newman and Mr. Farrell explain how PrimaFit includes numerous features that result in a product with improved fit, securement, and performance compared to other market products (including PureWick). (Newman, ¶¶20-31; Farrell, ¶¶6-8.) PureWick’s documents reflect PrimaFit’s clinical advantages. (Newman, ¶¶22, 35-36; DTX149 at 25; Exs. 25-30; DTX142 (“trialed [PureWick] and hated it...PrimaFit is ‘clinically superior’”). PrimaFit’s clinical benefits including its ability to accommodate a wide range of patients was also discussed at trial. (*See* Tr. 585, 600-608, 679-683, 730-732, 374-375.)

In contrast, the PureWick product lacks features and is an inadequate alternative; caregivers should at least have a choice to use a PrimaFit. (Newman ¶¶32-41; Farrell, ¶¶7-8.) The FDA’s “Manufacturer and User Facility Experience” (MAUDE) database reports nearly 1000 negative incidents with PureWick including many entries for “leaking,” “skin tears,” “urinary tract infections,” “kidney infection,” and “rash.” (*Id.*, ¶¶42-44; Ex. 15.) PureWick’s documents reflect these and other problems. (Newman, ¶¶22, 35-36; Exs. 25-30.) Trial evidence likewise showed problems with leaking, skin tears, and irritation, and its inability to stay in place. (Tr. 731-732, 248-249, 263-264; DTX403, 404, DTX142.) It also appears that PureWick is suffering from supply issues and its customers cannot obtain its products, further threatening patients. (Farrell, ¶11.)

Indeed, Sage customers had been willing to pay [REDACTED] for PrimaFit due to

¹ While Sage has discontinued the PrimaFit product that was the subject of the lawsuit (JTX14) (Farrell, ¶3), *any* permanent injunction that would keep any competing Sage product from the market would disserve the public interest.

the features and clinical benefits it offered over alternatives, and these are what drive customer demand. (Tr. 682; Farrell, ¶¶6-7; Newman, ¶¶20-31.) Gohde admits that Sage is perceived as a market “innovator” (D.I. 339, ¶5), and the PrimaFit includes patented innovations. (Ex. 13; Ex. 14 at 3; Newman, ¶31.) Customers that were diverted from PrimaFit returned to it after experiencing problems (including increased CAUTI) with PureWick. (Farrell, ¶9-10; Ex. 15; DTX142.) Hospitals would also turn to other NIAs including diapers, bed pads, catheters, which PureWick repeatedly asserts would cause patient harm. (Tr. 684-685, 421, 727.) Increased CAUTI results in concerns for individual patients and impacts the healthcare system as a whole. (Farrell, ¶¶9-10.)

D. Sage Will Be Harmed By An Injunction

PureWick cannot establish that the balance of hardships between the plaintiff and defendant favors an injunction. *eBay*, 547 U.S. at 391. Because the adjudicated PrimaFit is off the market (Br. 8), PureWick “has not shown [defendant] is continuing to infringe. Thus, there is no hardship to [plaintiff] in the absence of an injunction.” *KFx Med. Corp. v. Arthrex Inc.*, No. 11-cv-1698-DMS, 2014 WL 11961953, at *3 (S.D. Cal. Feb. 18, 2014) Indeed, “any benefit that [PureWick] would receive from an injunction has already been realized” because the product is discontinued. *I-Flow Corp. v. Apex Med. Techs.*, 2010 WL 141402, at *2 (S.D. Cal. Jan. 8, 2010). Sage, however, will be harmed even if it no longer sells the adjudicated product because “an injunction may create harmful uncertainty as to what products [PureWick] may assert are covered.” *Xpert*, 2013 WL 6118447, at *13; *Ameritox v. Millennium Health*, 2015 WL 3825499, at *3 (W.D. Wis. June 19, 2015) (“injunctive relief...would place [defendant] under an ongoing microscope in a competitive marketplace with no likelihood of further infringement given its adoption of a new [product]”). The adjudged PrimaFit [REDACTED], and Sage has invested [REDACTED] in product improvements. (Farrell, ¶¶4, 5.) The “ongoing microscope” of an injunction

would harm Sage’s business, costing Sage the goodwill and reputation built with its customers, and drive away those who are uncertain as to what products the injunction covers.

E. Sage’s Other Urine Collection Product, The NIA Which PureWick Never Accused Of Infringement In This Case, Is Not At Issue

PureWick failed to show that the four *eBay* factors support any injunction at all. (*See* n. 1.) Yet, PureWick now seeks a “briefing schedule” and more pages to litigate whether PrimaFit 2.0, the product that is the subject of *PureWick v. Sage*, No. 22-102-MN (“PureWick II litigation”), should be subject to an injunction in this case. (Br. 23.) To support its request, PureWick misstates the facts in hopes of importing an alternately-designed Sage product—that launched nearly three years ago and removed numerous features that PureWick claims are infringing—into a would-be future proceeding in this case. PureWick tells a false tale of Sage “secretly launch[ing] a new version of PrimaFit” and “fail[ing] to advise...that it had discontinued sales of the PrimaFit product specifically at issue in this case.” (Br. 16, 13, 15-16, 22-23.) The true story is that PureWick knew about 2.0 for over a year (including its 2019 launch), but PureWick never added 2.0 as an accused product in *this case*, presented no infringement case for 2.0 to the jury, chose not to address 2.0 as an NIA, filed a separate action on 2.0, and did not even bother to address the features in its brief. (D.I. 232 at 1-4; D.I. 205 at 8-10.) 2.0 is not part of this case nor should it be.

PureWick’s claim that 2.0 was “secretly” developed and launched is false. (Br. 16.) Sage identified 2.0 as an NIA after receiving the claim construction Order in February 2021 and identified numerous documents about it including IFUs, specification drawings, and technical descriptions. (Ex. 12 at 83; D.I. 232, Ex. 111 at 48.) PureWick asked numerous witness about 2.0 in depositions with a deposition dedicated to 2.0 and its features (*See, e.g.*, D.I. 211, Ex. 50 at 18-21, 23-26, 130-148; D.I. 232, Ex. 114 at 290-292.) Moreover, PureWick learned that 2.0 launched in 2019 and asked for launch details (Ex. 10 at 272-275). In March 2021, PureWick even

performed an in-person inspection. (Ex. 9; Ex. 16.) PureWick knew the product was on the market in November 2021. (*Id.*) Yet, despite extensive discovery (including before final contentions were due), PureWick never tried to add 2.0 into this case or accuse it as an infringing product.

PureWick paints itself as a victim for supposedly not knowing that ***Sage stopped manufacturing the adjudicated PrimaFit*** (JTX14) in 2021, but PureWick's assertions are false:

PureWick's False Statements In Its Brief	The Record Evidence
<p><u>"[T]he evening before this brief was filed, Sage disclosed for the first time that it discontinued sales of '[t]he PrimaFit at issue at trial' after November 2021."</u> (Br. 15-16.)</p> <p><u>"Sage continued its tactics post-trial, by withholding until the night before PureWick filed this brief, that the PrimaFit at issue at trial (JTX-14) is no longer being manufactured for sale and apparently has not been sold by Sage since November 2021."</u> (Br. 8.)</p> <p><u>"Sage failed to advise the Court or PureWick that it had discontinued sales of the PrimaFit product specifically at issue in this case by November 2021."</u> (Br. 13.)</p>	<p>Sage's February 21, 2022 letter to the Court: "[T]he original PrimaFit product (accused of infringing the 508, 376, and 989 patents in the present litigation) <u>is no longer being manufactured for sale.</u>" (D.I. 277, Br. at 10 (emphasis original); <i>id.</i> at 2.)</p> <p>Sage's March 13, 2022, Damages Report: "Sage has produced updated unit sales, revenue, and cost of goods sold data for PrimaFit through <u>November 2021</u> I understand that the PrimaFit sales data excludes amounts after November 2021 because <u>the original PrimaFit product at issue in this lawsuit is no longer being manufactured for sale.</u>" (Ex. 11 at ¶7; Ex. 16.)</p>

PureWick knew 2.0 was sold in 2021 (Ex. 16), obtained (another) sample (Br. 22; Ex. 9), and filed a second lawsuit before trial. PureWick proffers no reason why it did not accuse the product here. PureWick's tactic is apparent: in this case, PureWick wanted to present its false narrative that 2.0 was not an "available" NIA and 2.0's presence on the market contradicted that. (D.I. 235 at 28; D.I. 237 at 9-10; D.I. 236, ¶¶67-68.) Indeed, rather than adding 2.0, PureWick filed a motion *in limine* seeking to "preclude evidence...that PrimaFit 2.0 is commercially available" and argued that Sage "failed to credibly explain how....the release of its PrimaFit 2.0 product ('2.0') is relevant to any issue that the jury will decide." (D.I. 286-19 at 10.)²

² PureWick criticizes Sage for narrowing the case by withdrawing 2.0 as an NIA (Br. at 11), but it

In any case, *PureWick should not be permitted to circumvent a trial on the merits by failing to accuse 2.0 during the litigation*. Contempt proceedings are for later-developed, infringing products that are not colorably different than the adjudicated product—not existing products the plaintiff failed to accuse. *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 882 (Fed. Cir. 2011) (test applies where “elements previously found to infringe has been modified”). “[I]t would be inappropriate to expand the jury’s verdict to encompass not only products which were identified at trial but also products that were not previously accused of infringing....[Plaintiff] can seek appropriate relief as part of a new action.” *St. Lawrence Commc’ns v. Motorola Mobility LLC*, 2017 WL 6268735, at *5 (E.D. Tex. Dec. 8, 2017); *Opticurrent v. Power Integs.*, 2019 WL 2389150 (N.D. Cal. June 5, 2019), *aff’d*, 815 F. App’x 547 (Fed. Cir. 2020) (plaintiff “cannot point to a single instance where the ‘not colorably different’ test was used to determine...products that already existed...but were not included in the infringement contentions”). The defendant “deserves the opportunity to litigate the infringement question at a new trial.” *Arbek Mfg. v. Moazzam*, 55 F.3d 1567, 1570 (Fed. Cir. 1995). Indeed, it would encourage gamesmanship to permit a party to circumvent a scheduling order requiring initial and final infringement contentions by accusing one product, obtaining a verdict, and then capturing unaccused devices via contempt proceedings.

In any case, though PureWick did not address the issue, *PrimaFit 2.0 is a new design* with a new structure, new materials, and new features including the removal of numerous features that PureWick claimed were infringing and requires its own claim construction and expert report analysis. (Ex. 17 at 175-184; Farrell, ¶4.) It is colorably different and does not infringe. The

was PureWick that filed a second lawsuit and moved to preclude testimony on 2.0 in this one. PureWick never objected when Sage indicated that it would not assert 2.0 as an NIA given the numerous other available NIAs for trial. (D.I. 296 at 17.) In any case, given that it was PureWick’s burden to establish the lack of NIAs, PureWick chose not to address the 2.0 in this case.

appropriate place to litigate those issues would be in the PureWick II litigation, not here.³

F. Any Injunction Should Be Stayed Pending Post-trial Motions And Appeals

If the Court determines an injunction is warranted, as specified in D.I. 321, Sage intends to move to stay any injunction until post-trial motions and subsequent appeals are complete. *Nken v. Holder*, 556 U.S. 418, 427 (2009). Sage believes the relevant factors support a stay including for reasons discussed herein and in Sage’s post-trial briefing. (*See, e.g.*, D.I. 332; Sects. I.A-D.)

II. ENHANCED DAMAGES ON PRIMAFIT SHOULD BE DENIED

PureWick seeks enhanced damages on PrimaFit, but they are “not to be meted out in a typical infringement case.” *Halo Elecs. v. Pulse Elecs.*, 579 U.S. 93 (2016). Rather, enhanced damages are “‘a ‘punitive’ or ‘vindictive’ sanction for egregious infringement behavior,’” which is “‘willful, wanton, malicious, bad-faith, deliberate, consciously wrong, flagrant, or—indeed—characteristic of a pirate.’” *Nox Med. Ehf v. Natus Neur. Inc.*, No. 1:15-CV-00709-RGA, 2018 WL 6427686, at *1 (D. Del. Dec. 7, 2018) (quoting *Halo*). “A jury’s finding of willful infringement is a prerequisite to enhancement of damages but is not by itself sufficient.” *Id.* Enhanced damages are the exception rather than the rule.⁴ *Halo* confirmed that “such punishment should generally be reserved for egregious cases.” 579 U.S. at 106. Courts routinely deny enhanced damages even where there is a finding of willfulness and deliberate copying. *Nox*, 2018 WL 6427686 at *4; *Green Mtn. Glass LLC v. Saint-Gobain Containers*, 300 F. Supp. 3d 610, 630-31 (D. Del. 2018). Courts typically consider the nonexclusive factors outlined in *Read Corp. v. Portec*, 970 F.2d 816 (Fed.

³ PureWick’s suggestion that 2.0 was subject to full expert discovery (Br. 11) is incorrect. Though PureWick bore the burden of establishing the absence of NIAs, it failed to show that the 2.0 NIA infringed in its opening report, but argued it was not “available.” (Ex. 17 at 181-184.) PureWick raised new infringement arguments on Reply, which Sage could not address. (D.I. 205 at 10.)

⁴ The rarity of enhancement is evident in this District. While numerous cases reject enhancement (*supra*), Defendant is aware of a single post-*Halo* case granting it, which involved very different facts. *SRI Int’l v. Cisco Sys.*, 254 F. Supp. 3d 680, 723-24 (D. Del. 2017) (defendant filed meritless sanctions motions, designated 53 deposition transcripts for trial, and raised “frivolous” arguments).

Cir. 1992), in determining egregiousness. Here, the *Read* factors weigh against enhancement. Just as in *Nox*, alleged copying occurred before the patents issued, Sage voluntarily discontinued the accused product, Sage presented good faith defenses including ones that were vindicated at the PTO. Moreover, PureWick delayed in filing suit and identified no actual litigation misconduct.

A. *Read* Factor 1: PureWick’s Years-Old “Copying” Evidence Was Inadequate

Read factor one considers whether there was deliberate copying; however, to favor enhancement, evidence of copying should be so “overwhelming or one-sided” such that it “demonstrate[s] egregious misconduct.” *Power Integrations v. Fairchild Semiconductor Int’l*, No. 08-cv-309-LPS, 2019 WL 3290369, at *10 (D. Del. July 22, 2019) (denying enhancement despite copying). Courts routinely find copying evidence inadequate to support enhancement. *See, e.g., id.*; *Nox*, 2018 WL 6427686 at *4; *Green Mtn.*, 300 F. Supp. 3d at 30-31; *Siemens Mobility. v. Westinghouse Air Brake Techs. Corp.*, No. 16-284-LPS, 2019 WL 3240521, at *8 (D. Del. July 18, 2019) (“while the jury was free to find that [defendant] copied, the evidence of copying is not overwhelming, nor is there any evidence of particularly egregious copying”). Here, PureWick’s “copying” allegations were legally inadequate (D.I. 332 at 21-22) and were not the type of “one-sided” evidence that warrants enhancement. PureWick’s copying theory relies solely on years-old, preissuance acts, and PureWick cites no case where a court ordered enhancement under such facts.

First, PureWick failed to present a legally cognizable claim of copying as explained in Sage’s post-trial motions. (D.I. 332 at 21-22.) PrimaFit launched in 2017 (Tr. 605), and PureWick’s “copying” allegations stem from acts in 2016—three years before the 376 and 989 patents issued in 2019. (Br. 3-7.) PureWick alleges that, in 2016, Sage “copied” an unidentified and unpatented PureWick product. However, “[e]vidence that the defendant copied the plaintiff’s product prior to the issuance of the plaintiff’s patent is inadmissible...because pre-issuance conduct is not relevant to willfulness” and prejudicial. *Sonos v. D&M Hlds*, No. 14-1330-WCB,

2017 WL 5633204, at *3 (D. Del. Nov. 21, 2017); *bioMerieux, S.A. v. Hologic, Inc.*, No. 18-21-LPS, 2020 WL 759546, at *12 (D. Del. Feb. 7, 2020) (“‘A party cannot be held liable for ‘infringement,’ and thus not for ‘willful’ infringement, of a *nonexistent patent*.’”). Indeed, in *Bioverativ Inc. v. CSL Behring LLC*, No. CV 17-914-RGA, 2020 WL 1332921, at *2-4 (D. Del. Mar. 23, 2020), the court dismissed pre-issuance copying allegations pre-trial, holding that “[c]opying a product which is not protected by the patent laws is not illegal and does not constitute infringement” and “there can be no willful infringement before a patent issued.” In both *Nox* and *Siemens*, the courts declined to enhance damages because the copying allegations predated the patents’ issuance. *Nox*, 2018 WL 6427686 at *3 (rejecting copying evidence “because the actions pre-dated the issuance of Plaintiff’s patent”); *Siemens*, 2019 WL 3240521, *8 (no enhancement where defendant “launched its product ... before the...patents issued...”).^{5, 6}

Second, “evidence of copying...is legally irrelevant unless the [product] is shown to be an embodiment of the claims.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1366 (Fed. Cir. 2001). Here, PureWick presented no evidence that Sage had access to any patented PureWick product. (D.I. 332 at 23-26.) While PureWick lauds itself for its products, there was no proof any were patented—much less those from 2016. PureWick asserts that, in 2016, it sent products to Sage, but it presented no evidence of what those products were or that any were patented (much less that anyone involved in the PrimaFit design accessed them). To the contrary, PureWick’s witnesses testified that it made “hundreds and hundreds” of versions (Tr. 173, 291, 297), and Dr. Newton did not know what products were provided. (Tr. 224, 257-58 (“Q. So you

⁵ *Arctic Cat v. Bombardier*, 198 F. Supp. 3d 1343, 1350 (S.D. Fla. 2016) is inapplicable because it does not involve unsubstantiated allegations of pre-issuance copying.

⁶ At trial, PureWick alleged copying of a three-year old patent application (and dropped its product copying claims due to failure of proof, Tr. 660, 664-65, 1028). PureWick now drops its allegations about the patent application, which is legally irrelevant as well (*see* D.I. 332 at 22-23).

have no personal knowledge of what version wick was sold to Sage...? A. Correct.”; “Q. So you’re not sure what the timing was on any particular version of any wicks that were sold or provided to Sage; correct? A. That is correct.”) The PrimaFit designer likewise did not know. (Tr. 608.)

And PureWick’s brief highlights its inability to identify a single patented feature that was “copied.” PureWick claims that Sage “moved to cylindrical designs” and that Sage used “only one point of suction.” (Br. 6, 7.) But PureWick did not invent these features; they were ubiquitous in the prior art including in the invalidated 508 prior art patent. (*See, e.g.*, JTX1, Fig. 1; DTX21, Figs. 2-4; DTX9, Fig. 1, DTX7, Fig. 1, DTX16 at Fig. 1A; Ex. 4 at 7, 19, 22, 26.) The PrimaFit designer explained how she came to include those features based on constraints presented by the female anatomy (Tr. 591-93, 597)—not because of PureWick.⁷ PureWick’s attorney argument that PrimaFit prototypes appear “nearly identical” to an unidentified “PureWick product” is not evidence and is misguided. (Br. 7.) Whether prototypes are similar to an unknown PureWick version is irrelevant (and not true). (Tr. 586-595; DTX187.) With regard to PrimaFit itself, PrimaFit does not share a single component with PureWick’s four-component product.⁸ (Tr. 608-609, 635, 768-775; JTX14; JTX13.) Superficial look-a-like comparisons do not establish copying, *Sonos*, 2017 WL 5633204, at *3, particularly given Sage patented the PrimaFit design. (Ex. 18.)

The evidence was not “overwhelming and one-sided.” Numerous witnesses testified that Sage’s initial interest in PureWick dissipated once Sage conducted its own due diligence and learned PureWick’s problems. (Tr. 749-750, 243-245, 332-333, 884-885; DTX198; DTX403.) At

⁷ PureWick claims that there was an “accelerated development” of PrimaFit. (Br. at 4, 7.) But it took a year from the start of the PrimaFit development (by Sage’s engineer who held an advanced degree in bioengineering) until the final design and product launch. (Tr. 598, 605.)

⁸ PrimaFit is innovative and its inventions have been found to be patentable over PureWick’s patents (e.g., Exs. 13&18; Ex. 14 at 3), further demonstrating the lack of copying. *See Chugai Pharm. v. Alexion Pharm.*, No. 1:18-cv-01802-MN, D.I. 380 at 17-19 (D. Del. 2021).

the outset, Sage sought to design a product that was better than other products on the market including PureWick (Tr. 583-586, 597-598, 605-610; DTX903; DTX187.) Sage never copied (Tr. 610); indeed, the “copying” evidence that PureWick cites involves abandoned prototypes and documented PureWick failures. (Tr. 634-635; PTX23.4 (“#12...The problem...was that the suction wasn’t strong enough...it absorbs too much liquid+stays too wet”, PTX23.5 (“#14...never actually tested it”).) The PureWick “didn’t work well” and failed to capture urine consistently. (*Id.*; Tr. 634; DTX404; Exs. 25-30.) That Sage tested PureWick—a product on the market with no secret components (Tr. 255)—along with numerous other products was not extraordinary but standard engineering practice with the “intent...to make a superior product.” (Tr. 607-608; DTX149; DTX141.) The un rebutted expert testimony confirmed that “Sage acted consistently with the standard of behavior in the industry” (Tr. 812-813)—the very test that shows enhancement is unwarranted. *Siemens*, 2019 WL 3240521, *8, n. 9. PureWick itself deconstructed PrimaFit and concluded that it has “superior components.” (DTX149 at 25; Tr. 377-378.)

PureWick’s unsubstantiated attorney arguments are inconsistent with the evidence.

PureWick spends pages narrating a fictional account of a third party named Greg Davis—who PureWick never deposed, who never testified at trial, and who has not been employed by Sage for years and left before the PrimaFit design was even finalized—as the nefarious actor who “directed” PrimaFit product development. (Br. 1, 5-7; Alexander Decl.) There was no record evidence that Davis received or conveyed any “confidential” PureWick knowledge or participated in the final PrimaFit design, much less that he “dictated product design.” To the contrary, the PrimaFit design engineer testified that Davis was not her boss (“Q. Mr. Davis was your manager, correct? A. No.”) and that she was responsible for the final PrimaFit design after detailing her extensive independent development. (Tr. 615-18, 616 (“Q....Davis worked with you in developing prototypes; correct?

A. No.... I was responsible as the lead engineer..... Q. But he gave you ideas for prototypes, right?

A. No.”; “Would Mr. Davis sometimes...give you guidance on which way to go with your design?

A. No, ...”).) Indeed, Davis was not employed by Sage when PrimaFit was finalized and launched and left years before the patents issued. (Alexander Decl.) Davis’s alleged statements about a non-implemented, early prototype (among dozens, see DTX903) are a sideshow, and enhancement cannot be based on speculative conduct of a mystery witness.

PureWick also reiterates its unsubstantiated allegation that someone (Davis) “breached” a wall that existed between the PrimaFit design engineer and Sage employees involved in discussion with PureWick. (Br. 4.) While numerous witnesses testified that there was a wall between the PrimaFit engineer and the business development group (Tr. 609, 749, 754), there was no evidence that any “wall breach” had occurred. The PrimaFit designer had no knowledge of any PureWick discussions or any PureWick patent or patent application (Tr. 609-10)—the only “confidential” item identified by PureWick (Br. 4). The only one to mention a “wall breach” was PureWick’s attorney during closing arguments, and his opinion is not evidence. In any case, if there were a “breach,” PureWick could have sued Sage for breach—something PureWick never did despite knowing all the same “facts” it inappropriately argued at trial. (D.I. 286-21.)

Sage’s development activities were exactly the sort of conduct that the courts in *Nox*, *Siemens*, *Power Integrations*, and others found did not favor enhancement.

B. Read Factor 2: Sage Had Good-Faith Defenses Throughout This Litigation And PureWick Lost The IPR On The 508 Patent

The second *Read* factor, whether Sage “formed a good-faith belief that [the patent] was invalid or that it was not infringed,” also weighs against enhanced damages. Sage made its good faith beliefs about invalidity and noninfringement known throughout the case. At trial, PureWick presented no evidence of *any* post-issuance willfulness by Sage—much less any allegations

regarding Sage's state of mind at that time. (D.I. 332 at 21.) And PureWick's motion fails to address any of Sage's good faith defenses developed after the 376 and 989 patents had issued or presented throughout this litigation, despite having served an interrogatory on this very issue. (Ex. 12 at 3-14, 29-84; Ex. 24.) The evidence shows that, from the start, Sage held a good faith belief that the patents were not infringed and invalid. (D.I. 12.) The Answer identified detailed reasons why Sage believed the patents-in-suit were not infringed and were invalid, including bases Sage raised at trial. (See *id.* at 40-50.) Sage explained why it did not infringe the patents-in-suit, how the 508 patent was invalid in view of Mahnensmith and Kuntz, and that the other patents were invalid in view of Van Den Heuvel and Suzuki. (*Id.* at 34-36, 41, 42; D.I. 53, 59-64; D.I. 43 at 3.)

Sage felt so strongly about these and other defenses that, in early 2020, Sage sent PureWick a letter reiterating its good faith beliefs that it was not infringing any valid claim of the patents and asked PureWick to dismiss the lawsuit, raising these same defenses (e.g., Mahnensmith, Van Den Heuvel, and Suzuki) as well as defenses based on a potential public use bar by PureWick. (Ex. 2.) Notably, Sage's good faith beliefs were vindicated in part by the Patent Office. In February 2022, the PTAB issued a final written decision (Ex. 4) concluding that the 508 claims were, in fact, unpatentable in view of Mahnensmith and Kuntz—the very grounds raised in Sage's Answer and its 2020 letter to PureWick. The PTAB agreed with Sage's understanding of the prior art and credited the testimony of Dr. Newman, finding her analysis “credible, well reasoned and entitled to significant weight.” (Ex. 4 at 36, 41, 43, 44, 55, 56.) In contrast, the PTAB concluded that “Jezzi's testimony...is not credible” and “unreasonable and contrary to what a [POSA] would understand.” (*Id.* at 38.) The PTAB criticized Jezzi's “series of unsupported leaps” and found his theories “based entirely on speculation, inconsistent with how a [POSA] would have understood [the art], and thus is not credible and give it little weight.” (*Id.* at 35.) Additionally, consistent with

Sage’s 407 invalidity arguments, the PTAB recognized the obviousness of using a wicking material as a patient-facing layer as early as 2009, rejecting arguments Jezzi presented at trial to distinguish obviousness in view of Suzuki. (*See, e.g., id.* at 52-55; Ex. 5 at 5, 29; Tr. 718-19, 944.)

Sage presented its good faith defenses throughout the case (Ex. 12 at 3-14, 29-84; Ex. 24) including its continued belief that PureWick’s patents are invalid due to an on-sale bar. (§C; Ex. 24 at 211-215, 220.) Notably, PureWick never moved for summary judgment of no invalidity on Mahnensmith, Van Den Heuvel, Suzuki, or its prior art products, and the Court denied PureWick’s motion of infringement of the 376 patent (D.I. 287 at 4.) Sage moved for summary judgment of noninfringement and invalidity (D.I. 204), and the Court found triable issues (D.I. 287, 54-55).

PureWick contends that Sage allegedly did not develop good faith defenses after it learned of PureWick’s patent application (in 2016). (Br. 7-8.) But, as explained (D.I. 332 at 22), knowledge of a patent *application* is irrelevant. One cannot infringe an application and “[w]hat the scope of claims in patents that do issue will be is something totally unforeseeable;” the claims of that years-old application could (and did) change. *State Indus. v. A.O. Smith*, 751 F.2d 1226, 1236 (Fed. Cir. 1985); *iFIT v. Peloton Inter.*, No. 21-507-RGA, 2022 WL 609605, at *2 (D. Del. Jan. 28, 2022). PureWick also argues that “Sage offered no evidence that [it] conducted a reasonable investigation” (Br. 8), but it is PureWick’s burden to prove. *Siemens*, 2019 WL 3240521, at *3. In any case, Sage, of course, did conduct a reasonable investigation as evidenced by its successful arguments. (Ex. 2; Ex. 4.) Moreover, trial testimony evidenced Sage’s belief that PureWick’s patent coverage was inadequate. (Tr. 883, 758.) PureWick criticizes Sage for not having “written policies” (Tr. 887) about freedom to operate opinions, but PureWick cites no law that requires “written policies.” *See also* 35 U.S.C. §298. This factor weighs against enhancement.

C. Read Factor 3: Sage’s Litigation Of Its Defenses And Case Narrowing Is Ordinary—Not Extraordinary—Litigation Conduct

Read factor 3 considers misconduct during the litigation. Misconduct weighing in favor of enhancement “generally involves unethical or unprofessional conduct by a party or his attorneys.” *Old Reliable Wholesale v. Cornell Corp.*, 635 F.3d 539, 549 (Fed. Cir. 2011). Heavily litigated cases do not amount to misconduct, but rather courts consider whether a party has “been sanctioned for misconduct.” *Power*, 2019 WL 3290369, at *9 (D. Del. July 22, 2019); *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 271 F. Supp. 3d 694, 699 (D. Del. 2017). PureWick identified no “unethical” conduct by Sage nor did PureWick obtain sanctions during the case. Instead, PureWick mostly criticizes Sage for the case narrowing that it requested. Sage’s assertions of its defenses—including those vindicated by the PTAB—were warranted, weighing against enhancement.

First, PureWick first complains about Sage’s invalidity defense based on the PureWick prior art including the public use and sale of the brown tape product. PureWick’s prior public disclosures and sales presented such a strong case of invalidity that it was the subject of a Sage summary judgment motion. (D.I. 204 at 13-21.) Yet, it was PureWick that repeatedly withheld information about those products, and Sage that repeatedly sought to compel accurate responses:

- In **February 2020**, Sage served interrogatories asking “when the claimed subject matter was first disclosed” including “circumstances surrounding [the] disclosure, sale, offer for sale, and use” (No. 5) and regarding “each version” of PureWick’s product and the dates of use and disclosure (No. 6). (D.I. 207, Ex. 11 at 18, 20.)
- By **July 2020**, PureWick had not answered so Sage moved to compel. (D.I. 65; D.I. 65-2 at 17-18.) The Court ordered PureWick to supplement in view of, e.g., information that early versions existed. (D.I. 72 at 28.) The Court ordered PureWick “to identify...products that were made, used, or sold, if they were sold or demonstrated publicly, then identify the date on that...” (*Id.*)
- On **September 22, 2020**, PureWick finally supplemented but, despite the Court’s Order, did not identify the first disclosure of its products. (D.I. 231, Ex. 120 at 15-16.) PureWick stated that it provided the “brown tape” product to Connect in “approximately September 2015,” but omitted that it had told Connect about the brown tape product in July 2015. (*Id.* at 19-21; DTX515; Tr. 233.) PureWick claimed that its first sale was in January 2016 (months after the July 2015 sale that it reported to Connect). (*Compare* D.I. 231, Ex. 120 at 21 with DTX515 at 1-2.)
- In **October 2020**, Sage sought information regarding the differences, if any,

between the versions of the PureWick products. (D.I. 207, Ex. 17.) Despite its current claim that there were “hundreds and hundreds” that “were all different” (Tr. 173, 297), PureWick did not identify any differences. (D.I. 207, Ex. 17 at 3-4.)

- On **February 11, 2021**, Sage contacted the Court to request a hearing on PureWick’s continued failure to produce complete information regarding the early disclosure and sale of PureWick’s products. (D.I. 123; D.I. 146.) Sage explained its belief that PureWick’s first sale was not “January 2016,” but rather July 2015. (D.I. 146 at 3.) PureWick later supplemented its responses, finally revealing that a “sale of a PureWick device was made to one individual on July 26, 2015.” (Ex. 19 at 24.) At trial, PureWick contended that this was false. *See infra.*
- On **April 6, 2021**, Sage moved to compel more information regarding the prior art products. (D.I. 146.) Judge Fallon reiterated that “PureWick...has an ongoing obligation to supplement” and “the court expects PureWick to comply with its obligation to supplement” as it learns of information. (D.I. 194, Pl. Ex. 11 at 63.) PureWick argued that Sage’s prior art evidence should be stricken. (D.I. 145.) Judge Fallon denied PureWick’s motion. (D.I. 194, Pl. Ex. 11 at 61:19-62:4.)
- On **April 13 and 15, 2021**, the last week of fact discovery (and after final invalidity contentions were due), PureWick finally made the Newtons available for deposition. The Newtons testified that PureWick had sold and demonstrated the “brown tape” product before the priority date and discussed sales in July 2015. (Ex. 22 at 217, 214-216, 196-208; DTX488; DTX395.) Ray Newton testified that the products during that time frame had the same relevant features despite having different colors. (*See* Ex. 21 at 204, 21, 45-50; D.I. 300; D.I. 312.)⁹
- Sage’s expert offered opinions on invalidity in view of those products (D.I. 209, Ex. 23 at 249-74), and Sage ultimately felt so strongly about it that it moved for summary judgment (D.I. 204 at 13-21.) As discussed below, the Newtons changed their testimony at trial suddenly claiming that there were no sales, the Connect disclosure was false, and the brown tape products were different. (D.I. 312.)

Despite PureWick’s claim that “Sage hid the ball” (Br. 8), it was PureWick’s repeated failure to disclose, withholding of information, and constantly-shifting litigation positions that was prejudicial to Sage and hampered Sage’s ability to pursue its invalidity defenses. Moreover, PureWick revealed that it had failed to preserve the PureWick legacy email server, which

⁹ PureWick complains that Sage did not ask Ray Newton at trial about the brown tape products being the same (Br. 10); however, PureWick ignores that, at trial, Newton suddenly claimed “they were all different.” (Tr. 297.) This is in sharp contrast to his deposition testimony where he testified that they were the same. (*See, e.g.*, D.I. 312 at 5-6; Ex. 21 at 52-53 (“Q.·..... [O]ther than the fact that the reservoir was made of silicone..., and the tape was brown rather than blue,...were there any other substantive differences...? A. I can't think of any.”)). Sage is not required to waste trial time questioning witnesses who changed their deposition testimony on nearly every topic.

contained critical information relating to Sage’s defenses. This was prejudicial particularly since PureWick decided not to reveal it until late in discovery. (Ex. 20; Ex. 12 at 77-78.) PureWick then exacerbated this prejudice by refusing to search for documents from the Newtons, claiming that they were “third parties” (Ex. 32) and then contrarily seating Dr. Newton at counsel’s table at trial.

Sage continues to believe (and preserves for appeal) that the 376/989 patents are invalid based upon PureWick’s public use and sale before the priority date. (D.I. 204 at 13-21.) PureWick’s expert never refuted Sage’s arguments on anticipation or obviousness. (D.I. 209, Ex. 25 at 216-218, 231-232.) Rather, PureWick argued it was entitled to an earlier priority date—which PureWick failed to prove (Tr. 1121-22)—and “experimental” use. (*Id.*) PureWick attempted to exclude this prior art numerous times prior to trial and was unsuccessful. (*See* D.I. 232 at 1-4.) PureWick finally succeeded in gutting Sage’s defense a week before trial (without filing a motion), resulting in Sage being precluded from relying on the brown tape product unless it had “pictures” of it. (D.I. 296 at 79-80, 90-91.) This hindered Sage’s ability to present its defense at trial particularly once PureWick’s trial witnesses recanted their deposition testimony. For example, at trial, the Newtons testified for the first time that their catheter products were never sold in 2015 despite having previously testified that they were (*see* D.I. 312 at 2-4), telling Connect they were (in July 2015) (DTX 515; DTX519), and having won the “Most Innovative New Product” of 2015 (*Id.*) Examples of this changed testimony is documented in D.I. 312, for example:

Mr. Newton’s Deposition Testimony	Mr. Newton’s Trial Testimony
<p>Q. And did you indicate in the award submission that <u>the PureWick female external catheter</u> was sold on July 26th, 2015?</p> <p>THE WITNESS: <u>Yes</u>.</p> <p>Q. Were you honest in your submission that the product was sold on July 26th, 2015?</p> <p>THE WITNESS: <u>Yes</u>.</p>	<p>Q. And did you indicate in the award submission that the PureWick female external catheter was sold on July 26, 2015?</p> <p>A. Yes, the dry dock was sold, <u>we sold them a dry dock</u>. (Tr. at 321.)</p> <p>Q. But the female external catheter product, the dry dock is not an external natural catheter, female external catheter whatsoever, right?</p>

Q. Okay. And did you make a sale of the product on July 26th, 2015? THE WITNESS: Well, that's the date that we put on the form, <u>so I would say so.</u> (Ex. 21 at 204-205.)	A. Well, my understanding was a PureWick product had to be sold, so we sold the PureWick product at that time. Because <u>we didn't have any of the wicks ready for sales at that time.</u> (Tr. at 322.)
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Second, PureWick complains that Sage “wasted” resources because Sage should have asserted PrimaFit 2.0 was an NIA at trial but did not “for strategic reasons only.” (Br. 11.) There is nothing improper about narrowing a case for trial, particularly with limited trial time. Indeed, “[t]he Court encourages—and expects—litigants to narrow their cases as trial approaches...” *Idenix*, 271 F. Supp. 3d at 700; *Bial-Portela v. Alkem Labs.*, No. 20-CV-786 (D. Del. May 16, 2022) (oral order). Here, Sage presented numerous NIAs at trial including ones that PureWick never disputed (D.I. 332 at 28), and Sage was not required to address yet another. And nothing prevented PureWick from litigating whether 2.0 was an NIA given it was PureWick’s burden.

Third, contrary to PureWick’s assertions, Sage never once asserted any claim construction argument regarding the term “casing” contrary to the Court’s ruling. Sage’s expert specifically stated he was following the Court’s construction. (Tr. 766 (“I assumed the Court’s construction.”), 770.) And he explained why—under the Court’s construction—the “layers of material” in PrimaFit did not satisfy it. (Tr. 771.) Sage did not argue a different construction during cross-examination (Br. 12), but asked PureWick’s expert to read what the patent-in-suit says. (Tr. 532-535.) PureWick’s after-the-fact complaints are not like *SRI*, where the defendant repeatedly offered a different construction. 254 F.Supp. 3d at 722. PureWick’s argument is also hypocritical given its *repeated* attempt to have its expert provide its excluded royalty opinion. (Tr. 380-388, 1090-1091.)

Fourth, PureWick states that Sage served reports from “legal experts” that were stricken. (Br. 12.) But the experts were not precluded from testifying (D.I. 287 at 32; D.I. 177 at 20), and there is nothing “vexatious” about experts having a law degree. In contrast, PureWick’s experts were excluded from testifying on several topics. (*See* D.I. 297 at 50, 54.)

Fifth, PureWick’s assertion that Sage’s unenforceability defenses (based on PureWick’s undue delay in bringing its claims, *see* Ex. 12 at 43-45) were “baseless” is meritless given that (1) PureWick filed and then withdrew a motion to strike the defenses after a Court hearing addressing the issue (D.I. 15, D.I. 45; D.I. 48 at 12-13); and (2) PureWick never moved for summary judgment on any. Again, that Sage narrowed its case for trial is not misconduct. *See* n. 15; *Idenix, supra*.

Sixth, PureWick asserts that Sage committed misconduct because it relied on “Van Den Heuvel prior art,” which it claims “was considered by the [PTO].” (Br. 12.) Van Den Heuvel (DTX12, WO2007/042823) was not considered by the PTO. (JTX2, JTX3.)¹⁰ Moreover, a patent may be found invalid “on the basis of a reference that had properly been before the patent examiner,” *IPXL Holdings v. Amazon*, 430 F.3d 1377, 1381 (Fed. Cir. 2005), and PureWick was wrong to mislead the jury into thinking it could not. (D.I. 332 at 18.) Indeed, the PTAB invalidated the 508 patent in view of Kuntz, which was before the PTO. (Ex. 4 at 64; JTX1, 1:13-27.)

Finally, PureWick falsely argues that Sage “hid the ball” because it “failed to advise...that it had discontinued sales of the PrimaFit product...” (Br. 13.) As explained in Section I.E., this is demonstrably false. Though Sage had no obligation to do so, it repeatedly advised PureWick that the product was not being manufactured. (Ex. 11, ¶7; D.I. 277, Br. at 10; Ex. 16.)

This was a heavily litigated case, and Sage engaged in ordinary litigation conduct despite the obstacles it faced from PureWick’s litigation tactics and its persistence in the face of adverse PTAB rulings. Sage was not “unethical” and was never sanctioned for misconduct. This factor weighs against enhancement. *Idenix*, 271 F. Supp. 3d at 700-01; *Power*, 2019 WL 3290369 at *9.

D. Read Factor 4: Sage’s Financial Condition And Size

Read factor 4 considers a “[d]efendant’s size and financial condition.” PureWick focuses

¹⁰ Moreover, DTX12 had a different disclosure than other art by the same inventor. (Tr. 871-73.)

on revenues of Sage’s parent company, Stryker, (Br. 13-14) but that is the wrong inquiry as Stryker is not the defendant. *Nox*, 2018 WL 4062626, at *5 (“Plaintiff did not sue [parent] Natus Medical...Rather, Plaintiff sued Defendant, a comparatively small corporation.”). Here, PureWick “offers no information about Defendant’s size or financial condition.” *Id.* [REDACTED]

[REDACTED], weighing against enhancement. (Farrell, ¶¶2-3.) The award should not “unduly prejudice [defendant’s] non-infringing business.” *Idenix*, 271 F. Supp. 3d at 701; *Carnegie Mellon v. Marvell Tech.*, 2014 WL 1320154, at *14 (W.D. Pa. Mar. 31, 2014).

E. Read Factor 5: Closeness of the Case

Read factor 5 considers the “[c]loseness of the case.” Courts generally find this factor does not support enhancement where, as here, the defendant had defenses that survived summary judgment. *See, e.g., Green Mtn.*, 300 F. Supp. 3d at 629; *Edwards Lifesciences AG v. CoreValve, Inc.*, 2011 WL 446203, at *12 (D. Del. Feb. 7, 2011); *Finjan, Inc. v. Blue Coat Sys.*, No. 13-cv-03999-BLF, 2016 WL 3880774, at *17 (N.D. Cal. July 2016). In *Vectura Ltd. v. GlaxoSmithKline LLC*, No. 16-638-RGA, 2019 WL 4346502, at *4 (D. Del. Sep. 12, 2019), the court noted:

I do not believe that Defendants’ defenses were so weak as to be meritless. Defendant presented both a noninfringement and invalidity defense. Defendants presented considerable evidence in support of their assertions of noninfringement. Defendants also presented an invalidity defense with prior art references that contain each and every claim element of the asserted claims..... and it made the case at least relatively close.

Here, the case was close despite the verdict. Before trial, Sage had prevailed on one of the patents-in-suit before the PTAB. (*See* Ex. 4.) On the 407 patent, the evidence shows a close question was presented because the primary disputed issued—whether it would have been obvious to use a wicking material as the patient-facing layer in a vacuum-assisted urine device—was something the PTAB had agreed with Sage in the IPR proceeding. (*See id.* at 53-55; Section II.B above.) And with respect to the 376 and 989 patents, Sage raised considerable, non-meritless

defenses of both noninfringement and invalidity, and PureWick did not even rebut Sage's invalidity defense based on Van Den Heuvel. (*See* D.I. 331, 332 at 16-20.) PureWick's only argument is based on the time for the jury to reach its verdict, but courts "do not think the length of jury deliberations is a meaningful metric." *Vectura*, 2019 WL 4346502, at n.3.

F. Read Factor 6: PureWick Delayed In Asserting Infringement

The sixth *Read* factor considers the "[d]uration of... misconduct." 970 F.2d at 827. PureWick's own delay in filing suit weighs against enhancement. *Siemens*, 2019 WL 3240521, at *8. As discussed in §I.A., PureWick delayed for years in alleging infringement or concerns with patent applications despite knowing of PrimaFit before its 2017 launch and contacting Sage repeatedly over the two years interim. (Ex. 8; Ex. 1; Ex. 6; D.I. 53 at 43-45.) This was a basis for Sage's equitable defenses. (Ex. 12 at 43-45.) Instead, PureWick sat idly by, having made the calculated decision to delay with no explanation (Ex. 1; Ex. 7 at 28-29), while Sage built the market for PrimaFit and invested millions in improvements. (Farrell, ¶4.) Moreover, that Sage "continued to market the products they sold even before Plaintiffs obtained the patents-in-suit...does not show that they subjectively intended to infringe." *bioMeriux*, 2020 WL 759546, *12.

G. Read Factor 7: Sage Discontinued The Accused PrimaFit Product

Read factor 7 considers "[r]emedial action by the defendant." PureWick claims that Sage took "no remedial action" to avoid infringement. (Br. 14.) But, as discussed in §I.E., PureWick ignores that Sage released an NIA in late 2019 (PrimaFit 2.0), identified it to PureWick as an NIA, provided extensive discovery on it, and yet PureWick never identified it as an infringing product in this case. Sage stopped manufacturing the PrimaFit at issue and now sells that different product. (Farrell, ¶¶5-6.) This good faith belief by Sage that its actions avoided infringement, known and unchallenged by PureWick, weighs against enhancement. *SRI Int'l v. Adv. Tech. Labs.*, 127 F.3d 1462, 1465 (Fed. Cir. 1997) ("attempts to design around ...show good faith").

H. Read Factor 8: Normal Competition Is Not “Motivation For Harm”

Read factor 8 considers “[d]efendant’s motivation for harm.” 970 F.2d at 827. Here, PureWick identifies no motivation to harm PureWick. Rather, all of the evidence at trial showed that Sage’s motivation was to release a better product than the PureWick (which had numerous problems), with better clinical results for patients. (Tr. 583-586, 634-35, 682, 749-750; Farrell, ¶¶6-8.) The motivation to develop a better product is to be encouraged, not punished. *Idenix* 271 F. Supp. 3d at 702. PureWick’s only argument is that Sage developed its “product to compete head-to-head against PureWick.” (Br. 14-15.) But “a profit motive” is not the “harm” contemplated by *Read* but evidences a “garden-variety infringement case.” *Greatbatch Ltd. v. AVX*, No. 13-723-LPS, 2018 WL 1568872, at *6 (D. Del. Mar. 30, 2018); *Green Mtn.*, 300 F. Supp. 3d at 630.

I. Read Factor 9: PureWick Points to No Evidence of Any Concealment

Read factor 9 considers “[w]hether defendant attempted to conceal its misconduct.” 970 F.2d at 827. This factor weighs against enhancement where, as here, the defendant “sold the accused product openly.” *Nox*, 2018 WL 4062626, at *6. PureWick was aware of PrimaFit before it even launched in 2017 and before its patents issued. (Ex. 1; Ex. 6; Ex. 8; Tr. 605.) PureWick claims that Sage had a duty to inform PureWick in 2016 that it was developing PrimaFit (Br. 15), but PureWick cites no law to support a competitor has such a duty. PureWick’s only other argument is its tired reference to the wall between the PrimaFit designer and the Sage employee involved in discussions with PureWick. (*Id.*) But, as discussed (§II.A.), there was no “wall breach” and, in any case, that is not evidence of *Read* “concealment”. *Nox*, 2018 WL 4062626, at *6.

III. THE MOTION FOR ONGOING PRIMOFIT ROYALTIES OVERREACHES

PureWick seeks an ongoing royalty for PrimoFit (JTX15) (Br. 23-25), but an ongoing royalty is inappropriate because PrimoFit does not infringe and the 407 patent is invalid. (D.I. 332 at 12-15, 18-20.) Moreover, PureWick’s theory that it is entitled to double the jury’s rate is wrong.

“[T]o determine the ongoing royalty rate, courts have used the *Georgia-Pacific* factors.” *Vectura*, 2019 WL 4346502, at *7. PureWick “bears the burden to show that enhancement of the jury’s rate is appropriate.” *Cioffi v. Google*, No. 2:13-CV-103, 2017 WL 4011143, *3 (E.D. Tex. Sept. 12, 2017). At trial, Sage’s expert, Thomas, presented evidence that the reasonable royalty for PrimoFit should be 1% based on the GP factors (Tr. 901-913) and finds no change in circumstances now (Thomas, ¶¶7-11). PureWick’s expert proffered no countervailing royalty because he failed to apportion. (D.I. 287 at 41-50.) The jury set a royalty of 6.5%. (D.I. 316 at 5.) Without any GP analysis or other support, PureWick now contends that it is entitled to double the jury’s royalty because its position is “strengthened by the jury’s findings on infringement.” (Br. 24.) But, as this District held in addressing PureWick’s caselaw, the hypothetical negotiation already “assumes that the asserted patent claims are valid and infringed.” *EMC v. Zerto*, No. 12-CV-0956-GMS, 2017 WL 3434212, *3 (D. Del. Aug. 10, 2017). Thus, there is “no material difference between the parties’ current situation and the one it was in at the time of the hypothetical negotiation.” *Id.* at *3; Tr. 894, 543; *Vectura*, 2019 WL 4346502, *7. PureWick’s only other reason for arbitrarily doubling the jury’s rate is that Sage “is willful.” (Br. 24.) But there was no finding of willfulness on the 407 patent (D.I. 316 at 3), and Sage maintains good faith defenses (D.I. 332). Regardless, “willfulness...[is] not the inquiry.” *EMC*, 2017 WL 3434212, at *5.

The rate can be enhanced if there was proof of “significant post-verdict change in economic circumstances between the parties” and the product’s success was attributed to the patented features. But PureWick presented no evidence of either that would warrant changing the jury’s rate—much less double it. *EMC*, 2017 WL 3434212, at *4. PureWick provided no evidence of changed economic circumstances or that any PrimoFit purchases were made due to any patented technology. (Tr. 672, 911.) And, that PureWick does not have a competing product (Tr. 375, 911-

912) weighs against an increase. *Vectura*, 2019 WL 4346502, at *8. The only evidence of an appropriate post-verdict royalty is the analysis of Thomas. (Thomas, ¶¶7-11.) And in similar cases, courts routinely limit the royalty to the jury's rate. *See, e.g., Vectura*, 2019 WL 4346502, at *7; *EMC*, 2017 WL 3434212, at *4. Thus, the jury's award of 6.5% ends the analysis. *SRI Int'l v. Cisco Sys.*, 930 F.3d 1295, 1311 (Fed. Cir. 2019).¹¹

Finally, PureWick's request for a royalty on products not more than colorably different from PrimoFit (Br. 23) is improper as no such products have been identified or assessed. *Godo Kaisha IP Bridge I v. TCL Commc'ns Tech. Hldgs*, No. 15-634-JFB, 2019 WL 1877189, at *4 (D. Del. Apr. 26, 2019) (ongoing royalties require proof "that the newly accused product is not more than colorably different...and that..[it] actually infringes"); *St. Lawrence*, 2017 WL 6268735, *5.¹²

IV. PUREWICK'S MOTION FOR SUPPLEMENTAL DAMAGES

Trial sales data went through November 30, 2021, for PrimaFit and December 31, 2021, for PrimoFit. (DTX751b,c.) PureWick's contingent request for supplemental damages *on PrimaFit* is unwarranted because there are no more damages on the adjudicated PrimaFit product as PureWick acknowledges (Br. 25). As explained in §I.E., "the PrimaFit sales data excludes amounts after November 2021 because the original PrimaFit product at issue in this lawsuit is no longer being manufactured for sale." (Ex. 11, ¶7; D.I. 277, Br. at 10; Farrell, ¶3.) *With respect to PrimaFit*, supplemental damages from January 1, 2022 through judgment (6.5%) depends on post-trial motions and appeals. (D.I. 332 at 12-15, 18-20.)

¹¹ PureWick's cited cases are distinguishable because there was evidence of changed economic circumstances and/or profitability tied to patented features. *See, e.g., VirnetX v. Apple*, No. 6:13-CV-211, 2014 WL 12672822, at *2-4 (E.D. Tex. Mar. 6, 2014) (increased success in licensing); *Paice v. Toyota*, 609 F. Supp. 2d 620, 629 (E.D. Tex. 2009) (increase in oil prices and new laws).

¹² PureWick also "reserves its rights" to seek an injunction on PrimoFit at some unknown future time (Br. 23, n. 10), but provides no bases for seeking such speculative future relief.

V. PUREWICK’S MOTION FOR PRE- AND POST-JUDGMENT INTEREST

With regard to prejudgment interest, a court can “limit prejudgment interest, or...deny it altogether,” where “the patent owner has been responsible for undue delay in prosecuting the lawsuit.” *Gen. Motors v. Devex*, 461 U.S. 648, 657 (1983). Here, PureWick delayed for years in filing suit, which warrants denial. *Crystal Semiconductor v. TriTech Microelecs.* 246 F.3d 1336, 1362 (Fed. Cir. 2001) (no prejudgment interest for 2-year delay). Moreover, while courts have awarded the prime rate, many have found the Treasury bill rate compounded annually (see 28 U.S.C. § 1961) adequately compensates. *Sun Ship, v. Matson Nav.*, 785 F.2d 59, 63 (3d Cir. 1986); *Symbol Techs., Inc. v. Proxim*, No. 01-801-SLR, 2004 WL 1770290, at *10 (D. Del. July 28, 2004); *Verinata Health, v. Ariosa Diags.*, No. 12-cv-05501-SI, 2018 WL 4849681, at *2 (N.D. Cal. Oct. 4, 2018). That rate is appropriate here given PureWick’s delay and its failure to show it “borrowed money at a higher rate...or...a causal connection between any borrowing and the loss of the use of the money awarded.” *Laitram v. NEC*, 115 F.3d 947, 955 (Fed. Cir. 1997). Sage’s expert calculated prejudgment interest using average yield rates for one-year maturity Treasury bonds, compounded annually, resulting in prejudgment interest of \$121,482. (Thomas, ¶¶3-5.)

With regard to post-judgment interest, its availability at the statutorily-mandated rate (\$1,281.77/day as calculated by PureWick, Br. 27) depends on post-trial briefing and appeals.

VI. PUREWICK’S MOTION TO AMEND THE JUDGMENT

PureWick’s request that the Court amend its judgment (D.I. 320) to render judgment against Sage on its “equitable counterclaims of unenforceability” and invalidity subissues (§112 on the 407 and anticipation of three claims) that were not litigated at trial. (Br. 29) should be denied. **First**, “[t]he scope of any judgment should conform to the issues that were actually litigated...” *Alcon Research v. Barr Labs.*, 745 F.3d 1180, 1193 (Fed. Cir. 2014). That is because “broad pleadings alone do not define the scope of judgment when only a subset of those issues

were actually litigated.” *Microsoft Corp. v. DataTern*, 755 F.3d 899, 911 (Fed. Cir. 2014). PureWick cites no case that arbitrarily requires entry of judgment on assertions “in the pre-trial order”¹³ or any case that requires judgment on non-litigated defenses. To the contrary, in *VirnetX Inc v. Apple Inc.*, 925 F. Supp. 2d 816, 849 (E.D. Tex. 2013), the court held that it “cannot and will not enter judgment upon claims and defenses that were not presented for consideration to the jury. There is no basis to enter such a judgment,. . . . The Court encourages and requires the parties to narrow their case for trial.” *See also Idenix*, 271 F. Supp. 3d at 700.¹⁴ Here, the issues litigated at trial were precisely those included in the Court’s Judgment (D.I. 320) including as the issues were required to be narrowed before trial once the trial time was limited to eleven hours (D.I. 296 at 38).¹⁵ **Second**, contrary to PureWick’s assertions, Sage did not present separate counterclaims, e.g., for §112 indefiniteness or anticipation of specific claims. Rather, for each patent, Sage had a single counterclaim for no liability. (D.I. 53 at 46-51, 51-57, 57-67.) Thus, the Court’s Judgment (D.I. 320) already reflects judgment in favor of PureWick and against Sage on those counterclaims.

Alternatively, as explained in Sage’s contingent motion (D.I. 332 at 30), if judgment is entered on unlitigated claims, then the Judgment should be amended to include judgment of noninfringement in favor of Sage and against PureWick on Claims 2-4, 6-8, 10-14 of the 376 patent, Claims 2-5 of the 989 Patent, and Claims 3-16 of the 407 Patent, which Plaintiff withdrew before trial. (D.I. 44 at ¶¶62, 87, 111; D.I. 308 at 10 (¶¶44-45).)

¹³ PureWick misrepresents the pretrial order. The Section 112 issue related to 407 claim 7, which PureWick withdrew (D.I. 286, 52; D.I. 296, 55). And the order never specified anticipation for 989 claim 6 or 407 claims 1 and 2 (D.I. 286 at 43) (also impacted by PureWick’s dropped claims).

¹⁴ PureWick’s cited cases are irrelevant. Two (*Asetek* and *Silicon Graphics*) relate to defendants who waived defenses in post-trial briefing or on remand. And the third case (*Strub*) related to JMOL on a counterclaim that defendant tried to withdraw after it put on its case.

¹⁵ Given time constraints, Sage withdrew its equitable defenses on the 376/989 in this case to further case narrowing (D.I. 302) and narrowed its anticipation defenses given that there was only time to address a single main prior art reference for each patent.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 26, 2022, a copy of the foregoing document was served on the persons listed below in the manner indicated:

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